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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-----------------------|
| 10/767,260 | 01/30/2004 | Yoshihide Matsuo | 04853.0108 | 6256 |
| 22852 | 7590 | 11/29/2006 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | | NOAKES, SUZANNE MARIE |
| ART UNIT | | PAPER NUMBER | | |
| | | 1656 | | |

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------------|-------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/767,260 | MATSUO, YOSHIHIDE |
| | Examiner Suzanne M. Noakes, Ph.D. | Art Unit 1656 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 September 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 6, 7, 9, 11, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7, 9, 11, 13 and 14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10 June 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>31 August 2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. The Art Unit location and the Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656, Examiner Suzanne Noakes.

Election/Restrictions

2. The Examiner notes the error from the previous Office action of Group IV, being drawn to claims 7-10, wherein the claims should have been recited as claims 11-12 for said Group, and as noted by Applicants on p. 7 of the Remarks.

3. Applicant's election of Group I in the reply filed on 19 September 2006 is acknowledged. It is noted that Applicant's have elected with traverse and the traversal is based on the fact that Applicants assert that Group I has been mischaracterized as being drawn solely to compounds from FERM BP-8417 (strain YM-2-23). While Applicants are correct to point out this misinterpretation of the Group this, however, is considered an incomplete response because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement. Rule 37 CFR 1.111(b) and 37 CFR 1.143 state that Applicant is required to specifically point out the reasons for which he or she bases his or her conclusions that a requirement to restrict is in error. In the instant situation, Applicants have merely pointed out a mischaracterization of one of the restricted Groups, but have not established any basis or arguments to refute the actual restriction of the claims into different Groups. Thus, the election has been

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treated as an election without traverse (see MPEP § 818.03(a)). The requirement is therefore made Final.

Status of the Application

4. The amendments to the claims and specification, respectively filed 19 September 2006 and 17 October 2006, are acknowledged. Claims 5, 8, 10 and 12 have been cancelled. Claims 1-4, 6, 7, 9, 11, 13 and 14 are pending with claims 6, 7, 9, 11, 13 and 14 withdrawn from further consideration for being drawn to non-elected subject matter. Claims 1-4 are subject to examination on the merits.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 31 August 2006 has been considered by the examiner. See signed and attached PTO-1449.

Drawings

6. The drawings were received on 10 June 2004. These drawings are replacement drawings of those filed 30 January 2004.

7. The drawings are objected to because Figures 17 and Figures 18 are represented on three and two different pages, respectively, while having the same figure designation. The figures should be labeled either as continuations on the appropriate pages (e.g. Figure 17 continued) or with a capital letter following the number (e.g. Figure 17A, 17B and 17C). If the later is selected, then Applicants must note this change in the Brief Description of the Drawings as well.

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Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because of the following informalities:
 - A. The specification references certain sequences found within the application, however, the proper sequence identifier (e.g. SEQ ID No:) has not been used throughout the specification. See for example p. 9, last three lines.

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9. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on p. 11. Removal of 'http://' from said link will overcome this objection. See MPEP § 608.01.

Appropriate correction is required.

Claim Objections

10. Claims 1-4 are objected to because of the following informalities: The term 'novel' as used in claim 1 is a subjective term. In the instant case, the novelty *may* only be relative due to the compounds discovery rather than its invention. Thus, the removal of said term would overcome this objection.

Claim Rejections - 35 USC § 112 – 1st paragraph

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
12. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism YM-2-23 (FERM BP-8417) is recited in the claims, it is essential to the invention. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the

microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public.

However, since a deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

Reference of Interest – Not Relied Upon

13. Matsuo et al. (Science, 2005, 307 :1598) – Post filing art of the compound described in the instant claims.

Conclusion

14. No claim is allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is

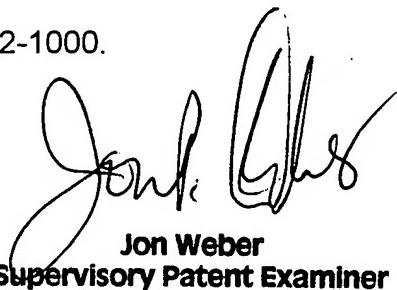
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571-272-2924. The examiner can normally be reached on Monday to Friday, 7.00am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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15 November 2006



Jon Weber
Supervisory Patent Examiner